

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Claims 8-15, 18 and 19 directed to the non-elected inventions are canceled without prejudice or disclaimer of the subject matter claimed therein. Applicants reserve the right to file a divisional application directed to such claims.

The only issue raised in the Official Action involves the rejection of Claims 1-7, 16 and 17 based on the disclosure in U.S. Patent No. 6,595,948 to *Suzuki et al.* That rejection is respectfully traversed for at least the following reasons.

The subject matter of this application pertains to a peritoneal dialysis apparatus. The peritoneal dialysis apparatus comprises at least one dialysis fluid container filled with a dialysis fluid, a dialysis fluid circuit containing at least one drained fluid container for recovering the dialysis fluid, fluid delivery means for delivering the dialysis fluid with the dialysis fluid container as a start point or the drained fluid container as an end point, input means for inputting various dialysis conditions (e.g., the number of cycles, the amount of infusion fluid per cycle, the total dialysis time, and the total amount of infusion fluid), and display means for displaying the inputted dialysis conditions. The apparatus performs dialysis by delivering the dialysis fluid to a patient by the delivery means and recovering the drained fluid.

According to one disclosed aspect, the dialysis apparatus permits selection of a therapy mode which calculates at least the staying time per cycle based on the total dialysis time, the amount of infusion fluid per cycle and the number of cycles which are inputted into the input means. As discussed in the present application, the ability to select a therapy mode in which at least the staying time per cycle is

calculated based on inputted dialysis conditions is advantageous from the standpoint of facilitating the use and operation of the peritoneal dialysis apparatus, concerns which are particularly relevant in the case of treatment performed outside a medical facility (e.g., at home).

Suzuki et al. discloses a peritoneal dialysis apparatus which, as discussed in the middle of column 18, permits input of various parameters necessary for peritoneal dialysis such as the treatment pattern, the initial amount of drained fluid, the amount of infused fluid, the stay time in the peritoneal cavity, the number of cycles, etc. However, *Suzuki et al.* is devoid of any disclosure that the apparatus permits selection of a therapy mode in which at least the staying time per cycle is calculated based on the total dialysis time, the amount of infusion fluid per cycle and the number of cycles which are inputted in the input means. It is thus respectfully submitted that independent Claim 1 is allowable.

Independent Claim 4 defines an aspect of the peritoneal dialysis apparatus involving the fluid infusion. As discussed in the background portion of the present application, if peritoneal dialysis is performed while the person is sleeping, it is possible that movement of the person may cause a temporary closure or occlusion of one or more tubes of the dialysis circuit, resulting in an alarm being generated. If the patient then shifts or moves again, the closure or occlusion of the tube(s) may be released so that the infusion procedure can continue. Thus, in such situations, the individual may be needlessly awakened or otherwise disturbed by the alarm.

As set forth in independent Claim 4, the peritoneal dialysis apparatus comprises means for calculating a fluid infusion time based on the amount of infusion fluid and the fluid infusion rate, means for deciding whether or not fluid

infusion is performed for a fluid infusion time exceeding the calculated fluid infusion time by more than a predetermined time, and means for generating an alarm indicating defective fluid infusion if it is decided that the fluid infusion exceeds the calculated fluid infusion time by more than the predetermined time.

Suzuki et al. mentions in column 19 various abnormal states such as the closure of the infusion line. However, *Suzuki et al.* does not disclose configuring the dialysis apparatus to determine whether or not fluid infusion is performed for a fluid infusion time exceeding a calculated fluid infusion time by more than a predetermined time, with an alarm being generated to indicate defective fluid infusion when the fluid infusion time exceeds the calculated fluid infusion time by more than the predetermined value. It is thus respectfully submitted that independent Claim 4 is also patentably distinguishable over the disclosure in *Suzuki et al.*

Independent Claim 6 is similar in some respects to independent Claim 4, but instead of addressing closure or obstruction of one or more of the infusion lines, Claim 6 addresses the possibility of closure or obstruction of one or more of the fluid drainage lines. As set forth in independent Claim 6, the peritoneal dialysis apparatus comprises means for calculating an amount of drainage fluid on the basis of the inputted dialysis conditions, and for calculating a fluid drainage time on the basis of the calculated amount of drainage fluid and the fluid drainage rate. In addition, the apparatus includes means for deciding whether or not fluid drainage is performed for a fluid drainage time exceeding the calculated drainage time by more than a predetermined time, and means for generating an alarm indicating defective fluid drainage if it is determined that the fluid drainage time exceeds the calculated fluid drainage time by more than the predetermined time. The dialysis apparatus

disclosed in *Suzuki et al.* does not include the features recited in independent Claim 6 for determining whether fluid drainage is performed for a fluid drainage time exceeding the calculated fluid drainage time by more than a predetermined time and for generating an alarm when the fluid drainage time exceeds the calculated fluid drainage time by more than the predetermined time. Claim 6 is thus also allowable.

Independent Claim 16 is directed to an aspect of the peritoneal dialysis apparatus in which an individual under dialysis wishes to temporarily stop the dialysis treatment. As set forth in Claim 16, the apparatus includes means for selecting a temporary separation mode during therapy to temporarily stop the therapy, and means for displaying a residual staying time after the temporary separation mode is selected. An embodiment of this aspect of apparatus is described beginning in the middle of page 65 of the application in connection with the illustrations in Fig. 15. *Suzuki et al.* does not disclose means for selecting a temporary separation mode to temporarily stop the therapy together with means for displaying a residual staying time after the temporary separation mode is selected. It is thus respectfully submitted that Claim 16 is also allowable.

Finally, with respect to independent Claim 3, the claimed peritoneal dialysis apparatus comprises means for calculating a dialysis end time from a desired dialysis time while the inputted set-up therapy start time is taken as a preferential value. There is no disclosure in *Suzuki et al.* of calculating the dialysis end time from a desired dialysis time as the inputted set-up therapy start time is taken as a preferential value. Thus, the claimed peritoneal dialysis apparatus recited in Claim 3 is also patentably distinguishable over the disclosure in *Suzuki et al.*

All of the dependent claims in this application are allowable at least by virtue of their dependence from allowable independent claims. Thus, a detailed discussion of the further distinguishing aspects of the claimed apparatus recited in the dependent claims is not specifically set forth at this time.


Early and favorable action with respect to this application is respectfully requested.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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